IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, *et al.*,
Petitioners

v.

GLEN L. RUTHERFORD, *et al.*,
Respondents

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY IN SUPPORT OF THE PETITION FOR CERTIORARI

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October 16, 1978

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Cancer Society ("Society") respectfully requests leave to file *instanter* the within brief *amicus curiae* in support of the United States' petition for writ of certiorari. The interest of the Society and its participation in the "Rulemaking Proceedings On Laetrile" before the Food and Drug Administration ("FDA") (Petitioners' Appendix at 51a) and as *amicus curiae* without opposition in the proceedings on appeal in the United States Court of Appeals for the Tenth Circuit (Petitioners' Appendix at 10a), is as stated in the "Statement of Interest" in the attached brief.

By letter of October 10, 1978, the Solicitor General of the United States, Wade H. McCree, Jr., consented "to the filing of a brief *amicus curiae* on behalf of the American Cancer Society in the Supreme Court in this case."

By letter of October 6, 1978, the undersigned counsel for the Society contacted Mr. Kenneth Coe, Esquire, attorney of record for the *Rutherford* plaintiffs below, requesting the same consent. This letter was followed up by a phone call on the afternoon of October 11, 1978. Mr. Coe flatly refused to grant consent. In so doing he cited as his reason, the lack of cooperation and runaround which he had received from the FDA in the prior proceedings which, of course, have no bearing on the propriety of an *amicus* brief to the Supreme Court by the Society.

While the Society supports the position of the Petitioner, the United States, its brief presents a different perspective, one which is in keeping with the role of the Society.

The Society is a voluntary organization fighting cancer through balanced programs of research, education, patient service and rehabilitation. The American public and the medical profession look to the Society for the most up-to-date and accurate information about cancer. Without the widespread dissemination of accurate information, such as that provided by the Society, the goal of further reducing the ravages of cancer through early diagnosis and treatment would unquestionably be more difficult to achieve.

Inasmuch as early and proper treatment of cancer is a life-and-death matter, unjustified deviations from this desideratum are of concern to the Society. One of the areas in the forefront of public and professional questioning addressed to the Society pertains to unproven methods of cancer management, e.g., laetrile.

It is from this perspective that the Sociey approaches participation as an *amicus curiae* in this proceeding. The Society's brief is not a repetition of arguments made by the United States or, we anticipate, by the respondent, but rather deals with and contains matter related to the impact of the Court of Appeals decision excluding the terminally ill from the coverage of the federal drug laws, both on the terminally ill as well as on those with life-threatening illness. The Society's brief deals with the issues of the role of the federal government with respect to the regulation of drugs in a manner and from a viewpoint different from that of the other parties.

The Society believes, in view of the nature of the case at bar, and the arguments urged or anticipated from the parties, that its arguments and information will assist the Court in its decision on the petition and that the Society should therefore be granted leave to file its brief *amicus curiae* in support of the Government.

Respectfully submitted,

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October 16, 1978

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BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY IN SUPPORT OF THE PETITION FOR CERTIORARI

STATEMENT OF INTEREST OF THE AMERICAN CANCER SOCIETY

The American Cancer Society has a substantial interest in the outcome of this proceeding. Briefly stated, the American public and the medical profession look to the American Cancer Society to provide the most up-to-date and accurate information about cancer. Since early and effective treatment of cancer is a life and death matter, one of the areas in the forefront of the public and pro-

fessional questioning addressed to the Society pertains to unproven methods of cancer treatment. In its efforts to respond to the need for information in this area, the Society established a committee on unproven methods and maintains the world's largest reference center for the collection and dissemination of data concerning the subject. In furtherance of its obligation to the American public and the medical profession to uncover and disseminate the facts relating to unproven methods of cancer treatment, the Society participated in the Food and Drug Administration rulemaking proceeding which followed the legal parameters set by the Court of Appeals in *Rutherford* v. *United States*, 542 F.2d 1137, 1140-43 (10th Cir. 1974). (Petitioners' Appendix at 51d). The Society also participated as *amicus curiae* in the proceedings on appeal which are the subject of this petition for writ of certiorari (Petitioners' Appendix at 10a).

The outcome of the Government's petition for certiorari which the Society supports will be largely determinative of whether the protections provided by Congress to the American public in the Food, Drug and Cosmetic Act will survive or whether they will fall, depriving both the consumer and the practicing physician of the first line of defense established by Congress at the request of President Kennedy who stated:

> There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of . . . ineffective drugs.
>
> The physician and consumer should have the assurance from an impartial scientific source, that any drug or therapeutic device on the market today is safe and effective for its intended use . . . .

1962 U.S. Code Cong. & Admins. News at 4143-44. The impact of the *Rutherford* Court of Appeals decision on the federal drug standards of safety and efficacy will

obviously affect the Society in its role as primary information source to the general public and the medical profession for accurate information on unproven methods of cancer treatment.

Another indication of the impact of the *Rutherford* decision, should it stand, on the public, and on the Society as its information resource, lies in the resurgence since mid-1976 when the *Rutherford* suit became heavily publicized, of inquiries about a number of unproven methods of cancer treatment in addition to laetrile. Prior to the *Rutherford* publicity, some of these methods were quiescent for months or years or came to the Society's attention at long scattered intervals. Those unproven methods include, e.g., the biological theory of ironization; herbal remedies including one called essiac; chelation therapy and alleged vaccines combined with special diets.

If the Court of Appeals' decision is permitted to stand, it will open the floodgates and permit the public, particularly those with life-threatening illness who are choice prey, to be inundated by worthless and therefore unsafe and dangerous drugs. The Society's interest lies in speaking out for the continuation of the proper balance of manufacturer and consumer interests which currently exists in the statutory scheme relating to drugs. It would be a grave disservice to the public if this regulatory scheme were undermined on the basis of a Court of Appeals decision which we demonstrate below is unsound as a matter of law.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS BY REWRITING THE FEDERAL DRUG LAWS HAS SO FAR DEPARTED FROM THE ACCEPTED AND USUAL COURSE OF JUDICIAL PROCEEDING AS TO CALL FOR AN EXERCISE OF THIS COURT'S POWER OF SUPERVISION

A. From The Exercise Of Federal Authority Over Drugs Initially By The Act Of 1906, And As Amended, The Terminally Ill Lay Within The Special Protection Of The Acts

The medical and popular press in the early 1900's reflected the sense of the country at that time that the words cancer and terminal illness were interchangeable. E. Cuyler Hammond, D.Sc., Director of Statistical Research Section of the American Cancer Society, writing in 3 Cancer 417 (Butterworth & Co., London, 1958) described the public's impression of cancer in the first quarter of this century as "incurable" and further stated that this conception was shared by a large proportion of the medical profession. This impression was certainly borne out by the literature which reported the survival rate for, e.g., uterine cancer in 1900, to be as low as 2.8%.[1]

Although these statistics improved somewhat in that between 1935-1940, the five year survival rate for all sites of cancer combined had reached 25% and by

[1] T. S. Cullen, Cancer of the Uterus (1900). *See also*, E. C. Hammond, "Cancer Prevention of Comparative Risks", 19 Archives of Environmental Health 395 (1969); and *see* J. S. Bloodgood, "Responsibility of the Medical Profession for Cancer Education, with Special Reference to Cancer of the Cervix", 15 American Journal of Cancer 1579 (1931) ("cancer of the cervix is today predominantly a hopeless disease.").

1951 it had reached 32%,[2] even in 1967, public and physician reaction to the term cancer still equated it with a death sentence:

> Cancer has many unconscious meanings and fantasies associated with it. Whatever the unconscious feelings which it stirs, typically it is feared consciously as a process equated with suffering and certain death . . . People continue to think of cancer as 'the killer.'
>
> What is impressive is that the doctors themselves feel very much the same way. It was not patients who described the diagnosis as a 'death warrant' or 'a date of execution.' The internist who referred to cancer as an 'incurable disease with an inevitable demise' expressed a view which was not atypical.[3]

As late as the summer of 1977, in Hearings before Senator Edward Kennedy's Subcommittee on Health and Scientific Research,[4] Lewis Thomas, M.D., Director of the Memorial Sloan-Kettering Cancer Center, observed that "For many patients and their families, the very word cancer is perceived as a death sentence. It is widely believed to be an inexorable and agonizing process, with no way out but death." [5]

[2] E. C. Hammond, "The Possibility of Improving Cancer Cure Rates at the Present Time", Cancer, May-June 1957 at 581-82; Proceedings of the Third National Cancer Conference 910 (1957).

[3] Donald Oken, "What to Tell Cancer Patients: A Study of Medical Attitudes", *reprinted in* Weir, Ethical Issues in Death and Dying (1977) at 21.

[4] Hearings Before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, "Evaluation of Information on Which the FDA Based Its Decision To Ban The Drug Laetrile From Interstate Commerce", 95th Cong., 1st Sess. ["Laetrile Hearings"].

[5] Laetrile Hearings, *supra* at 13.

This "popular" belief contrasts strongly with the actual statistics relating to survival from cancer which show that today, due to earlier diagnosis and the steady improvement in surgical, x-ray and

The early concern of the public and the press that the "seriously" or "terminally" ill be protected from useless nostrums is perhaps best exemplified by a series of articles by Samuel Hopkins Adams published in Collier's Weekly in 1906. These articles sought to enlighten the general public regarding the effects of various patent medicines and provided substantial impetus for the 1906 legislation regulating drugs.[6] A segment of the series contained the following passage, entitled "Preying on the Incurables":

> Incurable disease is one of the strongholds of the patent-medicine business. The ideal patron, viewed in the light of profitable business, is the victim of some slow and wasting ailment in which recurrent hope inspires to repeated experiments with any "cure" that offers. In the columns of almost every newspaper you may find promises to cure consumption. Consumption is a disease absolutely incurable by any medicine . . . This is thoroughly and definitely understood by all medical and scientific men. Nevertheless there are in the patent-medicine world a set of harpies who, for their own business interests, deliberately foster in the mind of the unfortunate sufferer from tuberculosis the belief that he can be saved by the use of some absolutely fraudulent nostrum. Many of these consumption cures contain drugs which hasten the progress of the disease . . . Others are comparatively harmless in themselves, but by their fervent promises of rescue they delude the sufferer into misplacing his reliance and forfeiting

chemical approaches to the management of cancer, the ratio of patients alive after five years of disease is one in three. With even earlier diagnosis and prompt treatment, half of those who have cancer could be saved. *See* American Cancer Society, 1977 Cancer Facts and Figures.

[6] *See* Cramp, Nostrums & Quackery (1912) for a compilation of the Colliers articles and a discussion of their effect on the food and drug legislation of 1906.

> his only chance by neglecting those rigidly careful habits of life which alone can conquer the "white plague." One and all, the men who advertise medicines to cure consumption deliberately traffic in human life.[7]

The inclusion of several of the Collier's Articles in the Congressional Record [8] as well as numerous citations in the Pure Food and Drug Act debates of reported frauds perpetrated upon the victims of such serious illness as cancer, consumption and diabetes in the form of spurious claims for cures,[9] indicates a significant concern with those illnesses which in 1906 were "terminal" and by inference a determination by Congress that the "terminally ill" as a class would be protected by the legislation.

Given this background of concern over the coverage of the 1906 Act vis a vis cancer, consumption and other illness then considered fatal, the Congress expressed disbelief when the Supreme Court in *United States* v. *Johnson*, 221 U.S. 288 (1911), a case which concerned a purported treatment for cancer, over a strong dissent by Justice Hughes, held that the 1906 Act did not apply to misrepresentations of facts relating to the ability of a drug to treat or cure a disease, but rather, only as to whether the ingredients used in the drug were properly stated on the label.

In response to this opinion, President Taft, on June 21, 1911, in a message to Congress, urged action to protect the seriously ill against statements of curative effect on drugs that are contrary to fact and that seduce the ill away from proven medical treatments:

> An evil which menaces the general health of the people strikes at the life of the Nation. In my opin-

[7] 48 Cong. Rec., part 12, Appendix at 625-630.

[8] *Id.*

[9] See e.g., 40 Cong. Rec. 1416, 9073.

> ion, the sale of dangerously adulterated drugs, or the sale of drugs under knowing false claims as to their effect on disease, constitutes such an evil and warrants me in calling the matter to the attention of the Congress.
>
> Fraudulent misrepresentations of the curative value of nostrums not only operate to defraud purchasers but are a distinct menace to the public health. There are none so credulous as sufferers from disease. The need is urgent for legislation which will prevent the raising of false hopes of speedy cures of serious ailments by misstatements of facts as to worthless mixtures on which the sick will rely while their diseases progress unchecked.[10]

The Congress reacted to this call for action by passing the Sherley Amendment to the Act [Act of August 23, 1912, 37 Stat. 416, ch. 352] which provided that misstatements regarding curative or therapeutic effects of a drug or device fall within the ambit of the Act.

In commenting upon the Sherley Amendments to the Act in the 1913 Report of the Bureau of Chemistry, Bureau Chief Carl L. Alsberg notes the early successes of the Amendment in terms of the curative claims found on medicinal labels. According to Alsberg, "Claims that preparations are cures for such serious diseases as tuberculosis or cancer do not appear on the labels as often as formerly." [11]

The reach of the protection of the statute to those who suffer from untreatable or incurable disease is apparent from the opinion of Justice Hughes upholding the Sherley Act Amendment to the 1906 Act in *Seven Cases . . . Eckman's Alternative et al.* v. *United States*, 239 U.S.

[10] 48 Cong. Rec. 11322 (1911). *See also*, Belmont Laboratories v. FTC, 103 F.2d 538 (3d Cir. 1939).

[11] Federal Food and Cosmetic Law, Administrative Reports, 1907-1949, CCH, Food Law Institute Series (1951).

510, 514 (1916). Justice Hughes, speaking for the Court, specifically upheld the following libel as a matter subject to prosecution under the Act as amended:

> [The label] conveys the impression to purchasers that said article or drugs will cure tuberculosis, or consumption, whereas, in truth and in fact, said article of drugs would not cure tuberculosis, or consumption, *there being no medicinal substances known at present which can be relied upon for the effective treatment or cure of tuberculosis, or consumption.* (emphasis added).

The concern of Congress that the protection of the Food, Drug and Cosmetic Act be extended not just to "healthy" consumers or those with life-threatening illness, but also to those with a terminal or fatal illness is also present in the Congressional debate on the 1962 amendments to the Act—which added the effectiveness requirement for new drugs.[12] Language in the debates reflects an understanding that the Act would apply to experimental drugs used to treat "cancer in its last stages." [13] Senator Eastland, another proponent of the bill, also assumed that drugs administered for "fatal diseases, such as cancer," would be subject to the Act's requirements, noting that approval of such drugs would be appropriate even though they might only prolong life or alleviate suffering.[14]

In view of this Court's interpretation of the amendments to the 1906 Act as progressively strengthening and

[12] *See* Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609 (1973). With respect to the concern regarding cancer demonstrated in the debates on the 1938 amendments to the Act, *see e.g.*, 79 Cong. Rec. 5023 (1935) (remarks of Sen. Copeland); 83 Cong. Rec. 7786-89 (1938) (remarks of Rep. Phillips and Rep. Lea).

[13] 108 Cong. Rec. 17399 (1962) (remarks of Sen. Kefauver, Chairmen of the committee reporting the bill).

[14] 108 Cong. Rec. 17401 (1962) (remarks of Sen. Eastland).

extending that law's protection of the consumer,[15] and the continuing evidence of concern by Congress with diseases that were considered "fatal", the protection afforded terminally ill patients under the Act has even greater force and effect today.

The plain language of the Act,[16] its legislative history set forth above, the holding of this Court that the Act is to be given a liberal construction [17] and should not be narrowed in coverage "short of the point where Congress indicated it should extend",[18] all point out the error inherent in the Court of Appeals' decision which carved out an exception from the Act for terminally ill patients. The Court has usurped the role of the Congress by rewriting the Act. The departure of the Court of Appeals from the role of the judiciary parallels a similar departure noted by this Court in *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The petition for certiorari was granted in that proceeding to permit correction of that error; that same course of action is indicated here:

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices,

[15] *See e.g.*, United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 793-99 (1969); United States v. Dotterweich, 320 U.S. 277, 280-82 (1943); United States v. Sullivan, 332 U.S. 689, 697 (1938).

[16] Section 201(f) of the Food, Drug and Cosmetic Act provides in part:

> The term "new drug" means—(1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . .

[17] United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. at 798. And see United States v. Lee, 131 F.2d 464 (7th Cir. 1942).

[18] 394 U.S. at 801.

> clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. Strong indications from legislative history that Congress intended the broad coverage the District Court thought "ridiculous" should satisfy us that the lower courts erred in refusing to apply the Act's language as written. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with "efficacy" and "safety." Cf. United States v. Sullivan, 332 US 689, 693-695, 92 L Ed 297, 301, 302, 68 S Ct 331 (1948); United States v Dotterweich, 320 US 277, 283-284, 88 L Ed 48, 52-53, 64 S Ct 134 (1943).

394 U.S. 798.

II. THE COURT OF APPEALS DECISION CARVING OUT AN EXCEPTION FROM THE COVERAGE OF THE FEDERAL DRUG LAWS FOR THE TERMINALLY ILL IS IN CONFLICT WITH THE DECISIONS OF OTHER COURTS OF APPEAL

The Court of Appeals' conclusion "as a matter of law that the 'safety' and 'effectiveness' terms used in the statute have no reasonable application to terminally ill cancer patients, and have no established meaning when considered in that context" [19] is in conflict with *Rutherford* v. *American Medical Association*, 379 F.2d 641 (7th

[19] Petitioners Appendix at 3a.

Cir. 1967), *cert. denied*, 389 U.S. 1043 [20] and also with *Tutoki* v. *Celebrezze*, 375 F.2d 105 (7th Cir. 1967).[21]

The *Allen Rutherford* case involved an action for a permanent injunction against the FDA and others by a physician and a number of cancer patients requiring that agency and others to cease their interference with the distribution, for their use, of the alleged cancer drug Krebiozen. Krebiozen had not received new drug approval from the FDA and hence was unavailable in interstate commerce. The Court of Appeals "sympathetically viewed" the action as "an outcry of *hopeless*, suffering cancer victims." 379 F.2d at 642. However, the Court did not reach the conclusion that the Act does not apply to such "*hopeless*" cancer victims, but rather, in denying their claim for injunctive relief, held that the right to such relief must be accompanied by a showing that under the procedures established by Congress for the introduction of new drugs, the drug Krebiozen would be approved or exempted (grandfather clause application) by the FDA.

In the *Tutoki* case, the Court of Appeals was asked to issue a declaratory judgment that the approval and exemption provisions of the federal laws relating to food and drugs do not apply to cancer patients and the drug they seek,—Krebiozen. 375 F.2d at 106. The *Tutoki* Court, specifically faced with the issue whether the federal drug laws were appropriately applied to cancer patients, mirrored the conclusions of the *Allen Rutherford* court,—that the FDA procedures cannot be bypassed unless it can be shown that the FDA, if it acted upon Krebiozen, would have approved or exempted the drug.

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[20] Hereinafter referred to as the "Allen Rutherford" case to distinguish it from the Glen Rutherford case which is the subject of this petition for writ of certiorari.

[21] Hereinafter referred to as "Tutoki".

The *Allen Rutherford* and *Tutoki* opinions thus postulate the provisions of the drug laws as applying to "hopeless" cancer patients,—the exact opposite of the result urged by the *Glen Rutherford* Court of Appeals.[22] A conflict between circuits is present requiring the resolution of this Court.

III. THE COURT OF APPEALS HAS DECIDED AN IMPORTANT QUESTION OF FEDERAL LAW, NAMELY, WHETHER THE TERMINALLY ILL SHOULD BE EXCLUDED FROM THE COVERAGE OF THE FEDERAL DRUG LAWS, WHICH HAS NOT BEEN, BUT SHOULD BE SETTLED BY THIS COURT

A. Terminal Cancer Patients Require the Protection of the Act

The Court of Appeals in the *Rutherford* case poses the question:

> [W]hat can "generally recognized" as "safe" and "effective" mean to such persons who are so fatally stricken with a disease for which there is no known cure? [23] What meaning can "effective" have in the absence of anything which may be used as a standard. Under this record Laetrile is as effective as

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[22] *Cf.* United States v. Olsen, 161 F.2d 669 (9th Cir. 1947) in which the requirements of the federal laws relating to drugs were considered applicable to a patient/purchaser of a devise advertised as diagnosing, mitigating, treating, preventing or curing a variety of ailments.

[23] This finding flies in the face of administrative and court interpretation which has hitherto consistently found the Act and its safety and effectiveness provisions applicable to cancer patients. *See e.g.*, Hearings on S. 1552 Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary 87th Cong., 1st Sess. Part 5, at 2588 at which the Secretary of HEW explained the FDA's attitude as follows: "If the drug is offered for the treatment of progressive or life threatening diseases *such as cancer*, or if the drug is seriously toxic or has alarming side effects we now consider its effectiveness." (emphasis added). *See also*, Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), *cert. denied*, 414 U.S. 944.

> anything else. What can "effective" mean if the person, by all prevailing standards, and under the position the Commission takes, is going to die of cancer regardless of what may be done. (Petitioners Appendix at 6a).[24]

The Court of Appeal's focus is apparently restricted to "cure" and is thus too narrow in terms of the class it addresses,—the terminally ill.[25] Bernard C. Meyer in an article "Truth and the Physician" reprinted in *Ethical Issues in Death and Dying* (1977) at 53, observes that the "Physician's response once he can no longer arrest disease is to assuage discomfort and distress". A cure may not be possible, but other relief for the terminally ill may be, for example, pain control, appetite stimulation, tranquilization.

In the Laetrile Hearings it became clear that the purveyors of laetrile have moderated their claims for the substance in recent years. For the most part, it is no longer openly claimed[26] that laetrile cures cancer [al-

[24] There is inconsistency in the Court of Appeals finding that the terminally ill are excluded from the strictures of the Act while at the same time confiining the utilization of laetrile to an injection route.

[25] For the purposes of this petition, it is assumed that an objective standard to determine who is "termnially ill" can be formulated and applied. However, applicability of the term terminal to individual patients is fraught with uncertainty in the context of cancer patients and if the petition is granted, the unworkability of the exclusion of this class from the statute will be fully explored.

[26] Compare the remarks of Lewis Thomas, M.D., Director of the Memorial Sloan-Kettering Cancer Center at Laetrile Hearings pp. 13-14 ("It is no longer openly claimed that Laetrile cures cancer", although some of the leaflets and public releases hint broadly in this direction.") with the remarks of Senator Kennedy at p. 257: ". . . the thing that's interesting about your careful choice of words about the impact of this [Laetrile] would be you had no reluctance of using the word 'cures' or 'recoveries' in the transcripts here before the California case. It was a tape of the town meeting. And I'll just read: 'Some cases have undergone clinical arrests, or for other practical purposes, we might describe as cures or recoveries.'"

though this is the expectation of the cancer victims that turn to it]. The current thrust of the laetrile proponents seems to be that it will dramatically relieve pain, improve appetite, promote weight gain, reduce the odor associated with cancer, improve the cancer patients general sense of well-being, control or prevent cancer.[27]

The terminally ill are entitled under the Act to the assurance that the products they seek to use are effective not only for cure or treatment but also for these other purposes.

Cancer victims constitute a minority group in our society; terminal cancer patients constitute an even smaller minority, but like other groups, they have a right not to be exploited. In the case of cancer drugs, particularly the exercise of government power of protection, premarket clearance is not only reasonable, but necessary to protect the compelling public interest in effective cancer therapy, and in assuring that non-therapeutic drugs do what they say. In view of the widespread incidence of cancer, the serious consequences of the disease, the experience with the particular vulnerability of cancer patients and their families to promoters of easy money-making schemes labeled in mysterious scientific dress, it is imperative that the standards of consumer protection set forth in the federal drug acts be maintained.

[27] See e.g., Laetrile Hearings at pp. 13-14 (Dr. Thomas); J. A. Richardson, M.D. who prescribes laetrile at 246-247, 271-72 (prevention, control, pain relief, appetite increase, weight gain, feeling of well-being). Robert A. Bradford, Committee on Free Choice for Cancer Treatment at 295-297 (stimulation of appetite, weight gain, decrease or eliminate pain, bad odor, pallor). Mr. Bradford also stated at p. 295 that "Laetrile is not offered as a cancer cure. There is no cure for cancer . . . In the very best of instances it may effect a control—but not a cure—of cancer. . . ."). See also the opinion of the Commissioner of the FDA at Petitioners Appendix pp. 73a-78a.

Further, the Court of Appeals assumes that Laetrile by injection is safe.[28] This assumption is unsupported by the record before the Court. An awareness of the actual and potential toxicity of Laetrile has emerged in recent expressions of scientific opinion.[29] Of particular significance is the article "Laetrile Toxicity: A Report of Two Cases", Smith and Schein, 238 Journal of the American Medical Ass'n 1361 (Sept. 1977). This article describes a case of serious side effects relating to administration of laetrile by injection and the cessation of such side effects when the laetrile was withdrawn.

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[28] The Court of Appeals direction to the FDA to promulgate regulations relating to the use of laetrile by injection by the terminally ill, cannot be executed. The laetrile proponents have been unable to provide a consistent picture of what the components of laetrile is. The samples alleged to be laetrile seized and analyzed by the FDA have had differing chemical compositions. Specifically, Commissioner Kennedy testified at pp. 4-5 of the Laetrile Hearings that the substance "has no fixed identity in the literature of its own components. It also has no fixed identity in the hands of our analytical chemists who find that the amount of amygdalin and the ratio of its isometric forms varies widely in the samples of materials we had seized." *See also* the Commissioners Opinion at Petitioners Appendix at 182a-187a.

Compare, Durovic v. Richardson, 479 F.2d 242, 251 (7th Cir. 1973), *cert. denied*, 414 U.S. 944. In that case, the Court of Appeals, as one rationale for its decision that Krebiozen could not be generally recognized as safe even in the narrow sense of non-toxic by qualified experts found that as of "October 9, 1962, the identity and composition of Krebiozen was completely unknown."

[29] *See e.g.*, Jukes, "Laetrile For Cancer," 236 Journal of the American Medical Ass'n 1284 (1976); Humbert, "Fatal Cyanide Poisoning: Accidental Ingestion of Amygdalin," 238 Journal of the American Medical Ass'n 482 (1977) and Lewis, "Laetrile" 127 Western Journal of Medicine 55 (1977).

B. Approval Of Laetrile For The Terminally Ill Poses A Substantial Threat To Those Whose Cancer Is Merely Life-Threatening

Finally, approval of laetrile for the terminally ill would pose a substantial threat to those whose cancer was merely "life-threatening". This very real danger was noted by Dr. Lewis Thomas at the Laetrile Hearings at p. 14:

> It is often asserted that since Laetrile is not a particularly toxic substance, it should be made available to all patients who wish to use it as a matter of free choice. There is, however, a very real danger here. If, for example, children with early leukemia or sarcoma, or women with cancer of the breast, or young men with Hodgkin's disease, are persuaded to give Laetrile a trial before doing anything else, the outcome will almost certainly be death, in circumstances where appropriate therapy could be lifesaving.

Further, approval of laetrile for the terminally ill would give the appearance of an official imprimatur, and would encourage use of the drug by patients who could be helped by legitimate therapy. See the Commissioner's Opinion at Petitioners' Appendix p. 268a. James Harvey Young, a noted medical historian, testified on the basis of his study of past unproven cures that "[p]ermitting laetrile's use in terminal cases gives it a credence among the public at large that will expand its use in early cases, for people will prefer taking a 'vitamin' to confronting the surgeon's knife." Petitioners' Appendix at 269a. Dr. Samuel G. Klagsbrun, a psychiatrist who works with cancer patients at St. Luke's Hospital in New York, testified that "[p]ermitting laetrile to be used by any population of cancer victims would have the correlative effect of creating the misimpression in the minds of other cancer victims that the drug is, in fact, safe and effective for a broader population." Petitioners' Appendix at 269a.

Also, laetrile cannot be effectively restricted to a "class" of "terminally ill" cancer patients. The experience in this country in regulating other controlled substances, available for limited use (e.g., cocaine), highlights the impossibility of restricting laetrile to "terminally ill" cancer patients, and preventing broader promotion. Petitioners' Appendix at 269a-270a.

The dangers posed by approval of laetrile for the terminally ill are particularly clear in the case of children with cancer. Children constitute only one percent of the cancer cases in this country but cancer represents the most serious threat to childlife next to accidents. Childhood cancers are also the category in which the greatest success in long-term remission and "cures" have been made. Yet, the natural desire for parents to avoid the suffering for their child which is a part of conventional treatment makes this class a minority which requires protection from the loophole in the law advanced in the *Rutherford* Court of Appeals decision.

This need is illustrated by a recent Massachusetts case arising from a physicians request to have a child committed to the Department of Public Welfare for the purpose of providing necessary medical care (chemotherapy) for the treatment of leukemia. *Custody of A Minor*, S.J.C. No. P-1422, Mass. Supreme Court, July 10, 1978 affirming the decision of the Superior Court, Plymouth Division of April 18, 1978 in Civil Action No. 78-6916.

IV. OTHER ISSUES INHERING IN THE CASE WHICH REQUIRE THAT THE PETITION FOR CERTIORARI BE GRANTED

Since the Court of Appeals has rewritten the Food, Drug and Cosmetic Act in ways which significantly endanger the public health and in particular the health

of those whose illness is life-threatening as distinguished from terminal, and since that decision conflicts with the decisions of other Courts of Appeals, the grounds set forth in Arguments I-III *supra* are sufficient to warrant the grant of the Government's petition for certiorari.

However, it is anticipated that the respondents may argue in reply to the petition that if the Court of Appeals cannot be sustained on its exclusion of the terminally ill from the statute, it should be upheld on the other grounds not dealt with by that Court, but contained in the District Court opinion. It is anticipated that the grounds alleged will be (1) that the substance Laetrile is protected by the grandfather clause in the 1962 Act, and that (2) the right to take laetrile is constitutionally protected. If these arguments are raised, the American Cancer Society would argue in its brief on the merits that (1) Laetrile is a new drug which is not exempt under the 1962 Grandfather Clause from the statutory premarketing clearance requirements of the Act; and (2) that the use of Laetrile is not constitutionally protected, specifically that Congress does not exceed its recognized authority to protect the public health and welfare in prohibiting the interstate movement of any drug which is not recognized as safe and effective.

CONCLUSION

Statutes should be given their fair meaning in accord with the evident intent of Congress. *See e.g., United States* v. *Sullivan*, 332 U.S. 689 (1948) and *United States v. Raynor*, 302 U.S. 540 (1938). The Court of Appeals has departed from this principle by construing the Act in a way that conflicts with its plain meaning and statutory intent, thereby eroding the protections provided by the Act and posing a significant threat, particularly to those whose illness is life-threatening instead of terminal.

For these reasons, the Government's petition for a writ of certiorari should be granted by this Court.

Respectfully submitted,

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